

REMARKS

I. Preliminary Remarks

Claims 1-20 are now pending. It is not the Applicant's intent to surrender any equivalents because of the amendments or arguments made herein. Reconsideration and allowance of all of the claims in view of the following remarks are respectfully requested.

II. Drawings

The Examiner has objected to the drawings for an unacceptable top margin in FIG. 5, poor line quality in FIGS 3A and 3B, and legibility and orientation of reference characters in FIGS 1-10. The Examiner has requested a proposed drawing correction or corrected drawings. In response, Applicant submits herewith ten (10) sheets of proposed drawing corrections to Figures 1-10, in accordance with MPEP § 608.02(v), along with a separate letter to the Official Draftsperson pursuant to MPEP § 608.02(r). The proposed drawing corrections include an increase in the top margin in FIG. 5, clarification of lines in FIGS 3A and 3B, and clarification and re-orientation of reference characters in FIGS 1-10.

Approval of the proposed drawing corrections is respectfully requested. Formal corrected drawings incorporating the proposed corrections will be filed after a Notice of Allowance is received.

III. Rejections Under 35 U.S.C. §103(a)

Claims 1-20 were rejected as being unpatentable over Umen, U.S. Patent No. 5,963,967 ("Umen") in view of Microsoft Press Computer Dictionary Third Edition ("MPCD").

A. Basic Requirements of a *Prima Facie* Case of Obviousness

According to the guidelines set out in MPEP §2143, three basic criteria must be met:

First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

At a minimum, the first and third requirements of a *prima facie* case of obviousness have not been established by the Office Action. Specifically, the Office Action has neither established that the prior art references when combined teach or suggest all of the claim limitations, nor indicated where a suggestion or motivation to combine the reference teachings exists.

B. The §103 Rejections of Claims 1 through 7, and 20

With respect to claim 1 and claim 20, the Office Action asserted that Umen discloses the claimed invention except for a "customized database," but that MPCD teaches a document that is the equivalent of the claimed "customized database." The Office Action concludes it would have been obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the document management system of Umen with the document of MPCD. Applicant respectfully traverses this ground of rejection for the reasons set forth below.

1. *Microsoft Press Computer Dictionary does not teach a database.*

The Office Action asserts that a document is the equivalent of a database because (1) a document is defined as "any self-contained piece of work created within an application program" and (2) a spreadsheet or a graphic are as much a document as are a letter or a report, since they are each a "collection of characters." However, It does not follow that because a spreadsheet, graphic, letter or report are each a type of document, as asserted by the office action, a database is also a type of document. Unlike a document, a database typically comprises a schema, or organizational structure, not inherent in a document. Thus, a document is not the equivalent of a database. That the two structures are different is recognized even by Umen, which refers separately to databases and to documents. For example, col. 3, lines 33-39 of Umen describe that *documents* can be generated on the basis of information stored within a *database*, and that the *database* can be updated on the basis of information contained within the *documents*. Clearly, a document and a database management system are not equivalents.

Even if a document could be considered the equivalent of a database, Applicants respectfully point out that claims 1 and 20 do not merely recite a "database," as asserted by the Office Action. Rather, the claims recite a "database management system." A database management system typically comprises a collection of information organized in such a way that a computer program can quickly select desired pieces of data. A database management system typically also comprises a means, such as software, for organizing and managing the flow of information within one or more databases that are managed by the database management system. A database management system may include documents as part of the information it organizes, but a database management system is not the equivalent of a document.

As asserted by the Office Action, Umen teaches customized documents, and does not teach a customized database. However, Applicant respectfully

asserts for the reasons above that a database is not the equivalent of a document. Moreover, Umen fails to teach a database management system, as recited in the claims. Therefore, the combined teachings of Umen and Microsoft Press Computer Dictionary do not teach a customized database management system. Because the combined references do not teach or suggest all the claim limitations, claims 1 and 20 are nonobvious.

2. Claim 1 is additionally nonobvious because Umen does not teach “retrieving a set of rules associated with the anticipated use of the customized database management system.”

The Office Action asserts that Umen (col. 6, line 50 – col. 7, line 15) teaches retrieving a set of rules associated with the anticipated use of the customized database management system. Applicant respectfully disagrees. The cited portions of Umen teach the use of “text objects” for storing items of data related to a clinical study. Umen teaches that “text files” are files that contain information about a particular study that might be managed within a clinical studies database. A user can enter study data into a text file, and a user interface may be used to retrieve information from a text file and display it to a user in a particular format. However, the cited portion of Umen does not disclose retrieving a set of rules associated with the anticipated use of a database system. Therefore, claim 1 is nonobvious.

3. Claims 1 and 20 are additionally nonobvious because Umen does not teach generating a customized database management system according to the analyzing of an answer and rule set.

The Office Action asserted that col. 2, lines 25-68 of Umen teach analyzing a set of rules, and that col. 10, lines 45-55 disclose generating a customized database management system according to that analysis. Applicant respectfully disagrees with each of these assertions. Col. 2, lines 25-68 of Umen disclose handling rules, such as FDA rules, but the teachings are

limited to the handling of such rules to generate a *form* that adheres to the rules. The teachings do not embrace generating a *customized database management system* according to the rules.

Col. 10, lines 45-55 also discloses the generation of *forms* that comply with FDA or other administrative rules, but does not disclose creating a *customized database management system*. As explained above, a document is not the equivalent of a database management system. Neither is a method of generating a properly formatted form the equivalent of a method of generating a customized database management system. Therefore, claims 1 and 20 are nonobvious.

4. Claims 1 and 20 are additionally nonobvious because there is no suggestion or motivation to modify Umen or to combine Umen with Microsoft Press Computer Dictionary.

The Office Action stated that it would have been obvious to one skilled in the art to combine the document generation system of Umen with the "document" defined in MPCD at the time the invention was made. The Office Action indicated that col. 2, lines 55-56 of Umen describe a motivation for such a combination: providing a database that is in compliance with FDA clinical trials regulatory rules.

First of all, the cited portions of Umen do not describe what the Office Action purports. Rather, they describe the preparation of *documents* that are compliant with *document requirements* prescribed by regulatory agencies (Umen, col. 2, lines 64-67). Second, even if Umen did describe providing a *database* that is in compliance with FDA clinical trials regulatory rules, that would be one of the *results* of Applicants' invention, not a *motivation* to practice it. Therefore, claims 1 and 20 are nonobvious.

5. Claims 2-7 are nonobvious because they depend from claim 1.

Each of claims 2-7 depend from claim 1, and include at least one additional limitation thereto. Therefore, because claim 1 is nonobvious as explained above, claims 2-7 must also be nonobvious.

C. The § 103 Rejections of Claims 8 through 19

With respect to claims 8 and 15, the Office Action asserted that Umen discloses the claimed invention except for the claimed "customized database." However, the Office Action asserted that MPCD teaches "documents," and concluded that a document is the equivalent of a database, and that it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to combine the document management system of Umen with the document of MPCD.

Claims 8 and 15 are nonobvious in view of the cited references for the same reasons that claim 1 is nonobvious, as explained above.

Each of claims 9-14 and 16-19 depend from claims 8 and 15, respectively, and include at least one additional limitation thereto. Therefore, because claims 8 and 15 are nonobvious as explained above, claims 9-14 and 16-19 must also be nonobvious.

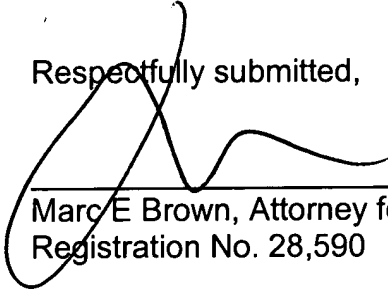
IV. Conclusion

Reconsideration of the above application is respectfully requested.

In view of the above, Applicant respectfully requests that a timely Notice of Allowance be issued in this case. Please charge any shortage in fees due in connection with the filing of this paper to Deposit Account 501946 and please credit any excess fees to such deposit account, referencing attorney docket number 69230-011-6806.

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Respectfully submitted,



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